K080635

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K080635.

Submitted By: Medtox Diagnostics, Inc.
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Date Prepared: February 10, 2009

Proprietary Name: PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System

Common Name: Colorimeter, Drugs of Abuse Test System

Classification Names:
The applicant test system regulatory classification is Class II; the Classification Panel is Clinical Toxicology (91) and Clinical Chemistry (75). Regulatory information applicable to the test system is provided below:

CFR Section	Product Code
862.2300, Colorimeter, Photometer, Spectrophotometer for Clinical Use	JJQ
862.3100, Amphetamine Test System	DKZ
862.3150, Barbiturate Test System	DIS
862.3170, Benzodiazepine Test System	JXM
862.3250, Cocaine and cocaine metabolite Test System	DIO
862.3620, Methadone Test System	DJR
862.3610, Methamphetamine Test System	DJC
862.3650, Opiate Test System	DJG
862.3100, Amphetamine Test System (Phencyclidine)	LCM
862.3870, Cannabinoid Test System	LDJ

Predicate Device: Triage® Meter (K973547)

Description of the Device
The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System consists of the PROFILE®-V MEDTOX*Scan*® Test Devices and the MEDTOX*Scan*® Reader. The MEDTOX*Scan*® Reader is an instrument used as an aid in determining the presence or absence of a colored line associated with the PROFILE®-V MEDTOX*Scan*® one-step drugs of abuse qualitative screening immunoassays for the detection of one or more of the following in human urine: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine, and THC (Cannabinoids) or their metabolites.

The MEDTOX*Scan*® reader scans the device and utilizes a contact imaging sensor (CIS) to capture relative line intensities. Software algorithms and barcodes are used to identify the type of device to be read, the analyte(s) associated with the device and whether the presence or absence of a line is associated with a negative or positive result. The results of the scans are

displayed on the MEDTOX*Scan*® screen or optionally can be printed. The PROFILE®-V MEDTOX*Scan*® Test Devices cannot be visually read.

Intended Use

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System consists of the PROFILE®-V MEDTOX*Scan*® Test Devices and the MEDTOX*Scan*® Reader. The PROFILE®-V MEDTOX*Scan*® Test Devices are one-step immunochromatographic tests for the rapid, qualitative detection of one or more of the following in human urine: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine and THC (Cannabinoids) or their metabolites. The PROFILE®-V MEDTOX*Scan*® Test Devices can only be used with the MEDTOX*Scan*® Reader. The MEDTOX*Scan*® Reader is an instrument used to interpret and report the results of the PROFILE®-V MEDTOX*Scan*® Test Device. The PROFILE®-V MEDTOX*Scan*® Test Devices cannot be visually read.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System is for *in vitro* diagnostic use and is intended for professional use only. It is not intended for use in point-of-care settings.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System detects drug classes at the following cutoff concentrations:

AMP Amphetamine (d-Amphetamine)	500 ng/mL
BAR Barbiturates (Butalbital)	200 ng/mL
BZO Benzodiazepines (Nordiazepam)	150 ng/mL
COC Cocaine (Benzoylecgonine)	150 ng/mL
MAMP Methamphetamine (d-Methamphetamine)	500 ng/mL
MTD Methadone (Methadone)	200 ng/mL
OPI Opiates (Morphine)	100 ng/mL
PCP Phencyclidine (Phencyclidine)	25 ng/mL
THC Cannabinoids(11-nor-9-carboxy-$^{\Delta}$9-THC)	50 ng/mL

Configurations of the PROFILE®-V MEDTOX*Scan*® Test Devices may consist of any combination of the above listed drug analytes. Refer to specific product labeling for the combination of drug tests included on that test device.

THE PROFILE®-V MEDTOX*Scan*® DRUGS OF ABUSE TEST SYSTEM PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY / MASS SPECTROMETRY (GC/MS), HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) OR LIQUID CHROMATOGRAPHY / TANDEM MASS SPECTROMETRY (LC/MS/MS) ARE THE PREFERRED CONFIRMATORY METHODS. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED.

The MEDTOX*Scan*® Reader includes a Positive QC Test Device, a Negative QC Test Device and a Cleaning Cassette. The MEDTOX*Scan*® Positive and Negative QC Test Devices are intended to detect errors associated with the MEDTOX*Scan*® Reader and a contaminated contact imaging sensor (CIS), and to verify that the CIS cleaning procedure using the MEDTOX*Scan*® Cleaning Cassette effectively removed any contamination (see "Troubleshooting" Section).

Discussion of Technological Characteristics:

a. Similarities and differences to predicate device

Both the applicant and the predicate test systems are used to detect the presence of drugs of abuse and their metabolites in human urine. In both systems, a urine sample is added to the test device and allowed to react for a specified period of time, after which an instrument is used to read the test device and interpret and display the test result. Both the applicant and predicate test devices are rapid single use disposable devices that use immunochromatographic lateral flow technology. The applicant test device utilizes gold-conjugated reagents to generate the reddish-purple test and controls lines, which are read by the instrument. The predicate test device uses fluorescent-conjugated reagents to generate control and test lines that are not visible and can be read only by the instrument.

Overall performance and characteristics of the MEDTOX*Scan*® and the predicate device, the Triage Meter, are summarized in Table 1 below:

Similarities		
Item	Device	Predicate
Intended Use	Determines qualitative positive or negative result from drug of abuse immunoassay screens.	Determines qualitative positive or negative result from drug of abuse immunoassay screens.
System Procedure	Sample is added to a single use test cassette, which is then read by instrument. Instrument is designed to read multiple single use test cassettes, one at a time.	Sample is added to a single use test cassette, which is then read by instrument. Instrument is designed to read multiple single use test cassettes, one at a time.
Measurement Method	Scans the single-use test cassette to detect a signal.	Scans the single-use test cassette to detect a signal.
Output	Outputs "positive," "negative," and "invalid" test results on paper printout or LCD screen.	Outputs "positive, "and "negative," test results on paper printout.

Differences		
Item	Device	Predicate
Single-Use Test Cassette	Produces colored lines on device.	Produces a fluorescent signal that is not visible to the instrument operator.
Assay Type	Competitive assay where concentration of drug is inversely related to the visible signal detected by the instrument.	Competitive assay where concentration of drug is inversely related to the fluorescent signal detected by the instrument.
Detection Method	Measures reflectance of visible lines on single use test cassette.	Measures fluorescent signal on single use test cassette.

Table 1. Comparison of Similarities and Differences for the MEDTOXScan reader and predicate device.

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

Numerous laboratory performance studies were conducted to determine the substantial equivalence of the MEDTOX*Scan*® test to the Triage Meter. These studies are as follows:

- Performance of the PROFILE®-V MEDTOXScan® Drugs of Abuse Test System around the specific cutoff for each drug was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 5 different intervals by 3 in-house operators using different readers (45 determinations for each level). Drug free urine was also tested on each interval. The results were interpreted at ten minutes by the MEDTOXScan® Reader and are summarized for each drug in Table 2 below:

Table 2. Sensitivity/Precision/ Distribution of Random Error

Sample Concentration (ng/mL)	% of Cutoff	Number of Observations	# Neg	# Pos	Sample Concentration (ng/mL)	% of Cutoff	Number of Observations	# Neg	# Pos
AMP (500)					BAR (200)				
0	NEG	45	45	0	0	NEG	45	45	0
100	20%	45	45	0	100	50%	45	45	0
250	50%	45	41	4	150	75%	45	32	13
375	75%	45	37	8	250	125%	45	0	45
625	125%	45	8	37	300	150%	45	0	45
750	150%	45	0	45					
BZO (150)					COC (150)				
0	NEG	45	45	0	0	NEG	45	45	0
75	50%	45	45	0	75	50%	45	45	0
112.5	75%	45	33	12	112.5	75%	45	24	21
187.5	125%	45	8	37	187.5	125%	45	0	45
225	150%	45	0	45	225	150%	45	0	45
mAMP (500)					MTD (200)				
0	NEG	45	45	0	0	NEG	45	45	0
100	20%	45	45	0	50	25%	45	45	0
250	50%	45	27	18	100	50%	45	34	11
375	75%	45	13	32	150	75%	45	8	37
625	125%	45	1	44	250	125%	45	0	45
750	150%	45	2	43	300	150%	45	0	45
OPI (100)					PCP (25)				
0	NEG	45	45	0	0	NEG	45	45	0
25	25%	45	45	0	6.25	25%	45	45	0
50	50%	45	37	8	12.5	50%	45	31	14
75	75%	45	4	41	18.75	75%	45	1	44
125	125%	45	0	45	31.25	125%	45	0	45
150	150%	45	0	45	37.5	150%	45	0	45
THC (50)									
0	NEG	45	45	0					
25	50%	45	45	0					
37.5	75%	45	39	6					
62.5	125%	45	0	45					
75	150%	45	0	45					

- Other Technical Performance Documentation for the MEDTOX*Scan*® include:

  - Influence of Temperature
  - Influence of Humidity
  - Factory Calibration
  - Electrical and EMC Testing
  - Validation and stability of QC Control Cassette
  - Validation and stability of Cleaning Cassette

- Analytical specificity (cross reactivity and interference) data are summarized below.

Related Compounds and Cross Reactants

The following metabolites and reacting compounds were evaluated for the specified test on the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System. Reference standards for the various metabolites and compounds were prepared in negative urine samples. Results are expressed as the minimum concentration required to produce a positive result in the indicated assay. Compounds that reacted with the test are listed first, and related compounds that did not react with the highest concentration tested are listed second as Negative at 100,000 ng/mL. The "% Cross-Reactive" values were calculated from the cut-off level for the calibrator used for each test (approximate 50% positive rate) divided by the lowest reported level found to react in the same test (greater than 66% positive rate).

Amphetamine- (AMP) (d-Amphetamine) 500 ng/mL

	Result	***% Cross-Reactive***
l-Amphetamine	Positive at 50,000 ng/mL	1%
Fenfluramine	Positive at 10,000 ng/mL	5%
MDA	Positive at 250 ng/mL	200%
Phentermine	Positive at 7,500 ng/mL	7%
Ephedrine	Negative at 100,000 ng/mL	None Detected
MDE (MDEA)	Negative at 100,000 ng/mL	None Detected
MDMA	Negative at 100,000 ng/mL	None Detected
l-Methamphetamine	Negative at 100,000 ng/mL	None Detected
d-Methamphetamine	Negative at 100,000 ng/mL	None Detected
Phenethylamine	Negative at 100,000 ng/mL	None Detected
Pseudoephedrine	Negative at 100,000 ng/mL	None Detected
Tyramine	Negative at 100,000 ng/mL	None Detected

Barbiturate-(BAR) (Butalbital) 200 ng/mL	***Result***	***% Cross-Reactive***
Allobarbital	Positive at 250 ng/mL	80%
Amobarbital	Positive at 800 ng/mL	25%
Barbital	Positive at 2,500 ng/mL	8%
Butabarbital	Positive at 400 ng/mL	50%
Cyclopentobarbital	Positive at 250 ng/mL	80%
Diphenylhydantoin (Phenytoin)	Positive at 2,000 ng/mL	10%
Pentobarbital	Positive at 300 ng/mL	67%
Phenobarbital	Positive at 1,250 ng/mL	16%
Secobarbital	Positive at 50 ng/mL	400%
Talbutal	Positive at 50 ng/mL	400%
Barbituric Acid	Negative at 100,000 ng/mL	None Detected
Glutethimide	Negative at 100,000 ng/mL	None Detected
Hexobarbital	Negative at 100,000 ng/mL	None Detected
Mephobarbital	Negative at 100,000 ng/mL	None Detected
Thiopental	Negative at 100,000 ng/mL	None Detected

Benzodiazepine-(BZO)(Nordiazepam) 150 ng/mL

	Result	***% Cross-Reactive***
Alprazolam	Positive at 100 ng/mL	150%
Alprazolam, 1-OH	Positive at 25,000 ng/mL	<1%
Clobazam	Positive at 75 ng/mL	200%
Clonazepam	Positive at 900 ng/mL	17%
Clorazepate	Positive at 200 ng/mL	75%
Desalkylflurazepam	Positive at 600 ng/mL	25%
Desmethylchlordiazepoxide	Positive at 1,000 ng/mL	15%
Desmethylflunitrazepam	Positive at 75 ng/mL	200%
Diazepam	Positive at 75 ng/mL	200%
Flunitrazepam	Positive at 50 ng/mL	300%
Lorazepam	Positive at 1,200 ng/mL	13%
Lorazepam glucuronide	Positive at 1,000 ng/mL	15%
Midazolam	Positive at 5,000 ng/mL	3%
Nitrazepam	Positive at 50 ng/mL	300%
Oxazepam	Positive at 200 ng/mL	75%
Oxazepam glucuronide	Positive at 2,500 ng/mL	6%
Temazepam	Positive at 90 ng/mL	167%
Temazepam glucuronide	Positive at 750 ng/mL	20%
Triazolam	Positive at 750 ng/mL	20%
Triazolam, 1-OH	Positive at 10,000 ng/mL	2%
7-Aminoclonazepam	Negative at 100,000 ng/mL	None Detected
7-Aminoflunitrazepam	Negative at 100,000 ng/mL	None Detected
Chlordiazepoxide	Negative at 100,000 ng/mL	None Detected
Flurazepam	Negative at 100,000 ng/mL	None Detected

Cocaine-(COC) (Benzoylecgonine) 150 ng/mL

	Result	***% Cross-Reactive***
Cocaine	Positive at 250 ng/mL	60%
Ecgonine	Negative at 100,000 ng/mL	None Detected
Ecgonine Methyl Ester	Negative at 100,000 ng/mL	None Detected

Methamphetamine-(mAMP) (d-Methamphetamine) 500 ng/mL

	Result	***% Cross-Reactive***
Ephedrine	Positive at 2,500 ng/mL	20%
Fenfluramine	Positive at 50,000 ng/mL	1%
MDE (MDEA)	Positive at 7,500 ng/mL	7%
MDMA	Positive at 1,150 ng/mL	43%
l-Methamphetamine	Positive at 7,500 ng/mL	7%
Phenethylamine	Positive at 2,500 ng/mL	20%
Phenylephrine	Positive at 25,000 ng/mL	2%
Procaine	Positive at 7,500 ng/mL	7%
d-Amphetamine	Negative at 100,000 ng/mL	None Detected
l-Amphetamine	Negative at 100,000 ng/mL	None Detected
MDA	Negative at 100,000 ng/mL	None Detected
Phentermine	Negative at 100,000 ng/mL	None Detected
Phenmetrazine	Negative at 100,000 ng/mL	None Detected
Pseudoephedrine	Negative at 100,000 ng/mL	None Detected
Tyramine	Negative at 100,000 ng/mL	None Detected

Methadone-(MTD) (Methadone) 200 ng/mL	***Result***	***% Cross-Reactive***
Buprenorphine (MTD Replacement)	Negative at 100,000 ng/mL	None Detected
EDDP (Primary metabolite)	Negative at 100,000 ng/mL	None Detected
EMDP (Secondary metabolite)	Negative at 100,000 ng/mL	None Detected

Opiates-(OPI) (Morphine) 100 ng/mL	***Result***	***% Cross-Reactive***
Codeine	Positive at 50 ng/mL	200%
Diacetylmorphine	Positive at 50 ng/mL	200%
Dihydrocodeine	Positive at 75 ng/mL	133%
Ethylmorphine	Positive at 50 ng/mL	200%
Hydrocodone	Positive at 400 ng/mL	25%
Hydromorphone	Positive at 800 ng/mL	13%
Levorphanol	Positive at 2,500 ng/mL	4%
6-Monoacetylmorphine	Positive at 350 ng/mL	29%
Morphine 3-β-D-Glucuronide	Positive at 75 ng/mL	133%
Morphine 6-β-D-Glucuronide	Positive at 500 ng/mL	20%
Nalorphine	Positive at 50,000 ng/mL	<1%
Norcodeine	Positive at 10,000 ng/mL	1%
Thebaine	Positive at 25,000 ng/mL	<1%
Apomorphine	Negative at 100,000 ng/mL	None Detected
Naloxone	Negative at 100,000 ng/mL	None Detected
Naltrexone	Negative at 100,000 ng/mL	None Detected
Oxycodone	Negative at 100,000 ng/mL	None Detected
Oxymorphone	Negative at 100,000 ng/mL	None Detected

Phencyclidine-(PCP) (Phencyclidine) 25 ng/mL	***Result***	***% Cross-Reactive***
4-Hydroxyphencyclidine	Positive at 7,500 ng/mL	<1%

Cannabinoids-(THC) (11-Nor-9-carboxy-Δ^9-THC) 50 ng/mL	***Result***	***% Cross-Reactive***
Δ^9 –Tetrahydrocannabinol	Positive at 100,000 ng/mL	<1%
Cannabidiol	Negative at 100,000 ng/mL	None Detected
Cannabinol	Negative at 100,000 ng/mL	None Detected
L-11-Hydroxy-Δ^9-THC	Negative at 100,000 ng/mL	None Detected
Δ^8 –Tetrahydrocannabinol	Negative at 100,000 ng/mL	None Detected

Interference Data

pH and Specific Gravity:
The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System was assayed with three negative clinical samples with pH values of 4.0, 7.0 and 9.0 ± 0.1. Each sample was assayed in triplicate. The pH samples were fortified with drug concentrations that were the maximum level to give a strong negative (95% or greater negative) result (10-50% of cut-off, see Sensitivity data), and the minimum level above the cut-off to give a strong positive (95% or greater positive) result (125-150% of cut-off, see Sensitivity data). All three pH samples gave negative results when fortified to the maximum strong negative level for each drug, and all gave positive results when fortified to the minimum strong positive level for each drug.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System was assayed with three samples with specific gravity values of 1.003, 1.015 and 1.030 ± 0.001. Each sample was assayed in triplicate. The specific gravity samples were fortified with drug concentrations as described above for pH to give strong negative and strong positive results. All three specific gravity samples gave negative results when fortified to the maximum strong negative level for each drug, and all gave positive results when fortified to the minimum strong positive level for each drug.

Common Drugs:
Drug free urine samples were spiked with drug concentrations that were the maximum level to give a strong negative (95% or greater negative) result (10-50% of cut-off, see Sensitivity data), and the minimum level above the cut-off to give a strong positive (95% or greater positive) result (125-150% of cut-off, see Sensitivity data). 100,000 ng/mL of the common drugs were then added to the preparation and assayed by the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System. If a common compound name is followed by the abbreviation "COC", "BAR" or "OPI", then it has cross-reactivity to the specified drug test (see "Related Compounds and Cross Reactants") and therefore was not assayed for interference for that drug test. Samples were evaluated in triplicate by in-house operators. None of the common drugs listed in the following table affected the expected results.

Table 3. Common Drugs Evaluated with the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System

Acetylsalicylic Acid	Chlorpheniramine	Morphine - **OPI**
Acetaminophen	Cocaine - **COC**	Phenobarbital - **BAR**
Brompheniramine maleate	Dextromethorphan	Phenytoin (Diphenylhydantoin)-**BAR**
Caffeine	Doxylamine	d-Pseudoephedrine
Carbamazepine	Ibuprofen	Salicylic Acid

Discussion of Clinical Tests Performed for Determination of Substantial Equivalence:

The accuracy of the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System was evaluated by assaying a panel of blind coded clinical urine samples containing varying concentrations of drugs and comparing to GC/MS or LC/MS/MS results. The samples were obtained from MEDTOX Laboratories and grouped in the following manner: Negative samples that screened negative by KIMS (Kinetic Interaction of Microparticles in Solution), and not confirmed by GC/MS; Below Cutoff Negative samples that fell between limit of detection or quantitation and 50% of cutoff; Near Cutoff Negative samples that fell between 50% of the cutoff concentration and the cutoff concentration; Near Cutoff Positive samples that fell between the cutoff concentration and 150% of the cutoff concentration; and High Positive samples that were greater than 150% of cutoff concentration. Drug concentrations were assayed by GC/MS or LC/MS/MS for BZO. Concentrations used to assign the cutoff ranges for each drug were determined by summing the GC/MS and LC/MS/MS levels measured for all test-specific analytes found in the sample. The testing was performed by in-house operators. The results were interpreted at ten (10) minutes by the MEDTOX*Scan*® reader. No false positives were observed in the absence of drug. The results are summarized in Table 4 below.

Table 4.
PROFILE®-V MEDTOX*Scan*® Drugs of Abuse System Results vs stratified GC/MS or LC/MS/MS Values

DRUG	P-V MEDTOX*Scan* Test System	No Drug	Low negative by GC/MS or LC/MS/MS (Less than -50%)	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (Between cutoff and +50%)	High Positive (greater than +50%)	% Agreement.
AMP (500)	Positive	0	0	4	5	41	96%
	Negative	40	5	0	2	0	92%
BAR (200)	Positive	0	0	3	4	36	100%
	Negative	40	3	2	0	0	94%
BZO (150)	Positive	0	0	1	4	41	100%
	Negative	40	3	3	0	0	98%
COC (150)	Positive	0	0	2	4	52	97%
	Negative	56	1	5	1	1	97%
mAMP (500)	Positive	0	0	1	3	40	98%
	Negative	40	4	3	1	0	98%
MTD (200)	Positive	0	0	2	3	40	98%
	Negative	40	4	2	1	0	96%
OPI (100)	Positive	0	0	3	5	44	100%
	Negative	46	2	2	0	0	94%
PCP (25)	Positive	0	0	3	10	30	100%
	Negative	40	1	1	0	0	93%
THC (50)	Positive	0	0	2	7	33	100%
	Negative	40	4	2	0	0	96%
All Drugs	Positive	0	0	21	45	357	98.5%
	Negative	382	27	20	5	1	95.3%

For samples giving preliminary positive results below the cutoff and negative results above the cutoff, the assayed values are detailed in the table below:

Table 5.

ACCURACY/SUMMARY of DISCORDANT RESULTS

Cutoff Value (ng/mL)	P-V MEDTOX*Scan* Test System	Drug or Metabolite GC/MS or LC/MS/MS Value (ng/mL)
500	AMP positive	Amphetamine at 277ng/mL
	AMP positive	Amphetamine at 352ng/mL
	AMP positive	Amphetamine at 368ng/mL
	AMP positive	Amphetamine at 463ng/mL
	AMP negative	Amphetamine at 504ng/mL
	AMP negative	Amphetamine at 667ng/mL
200	BAR positive	Butalbital at 126ng/mL
	BAR positive	Butalbital at 159ng/mL
	BAR positive	Butalbital at 184ng/mL
150	BZO positive	Alprazolam at 146ng/mL
150	COC positive	Benzoylecgonine at 114ng/mL
	COC positive	Benzoylecgonine at 121ng/mL
	COC negative	Benzoylecgonine at 180ng/mL
	COC negative	Benzoylecgonine at 278ng/mL
500	mAMP positive	Methamphetamine at 483ng/mL
	mAMP negative	Methamphetamine at 554ng/mL
200	MTD positive	Methadone at 148ng/mL
	MTD positive	Methadone at 176ng/mL
	MTD negative	Methadone at 250ng/mL
100	OPI positive	Morphine at 51ng/mL
	OPI positive	Morphine at 79ng/mL
	OPI positive	Morphine at 92ng/mL
25	PCP positive	Phencyclidine at 19ng/mL
	PCP positive	Phencyclidine at 21ng/mL
	PCP positive	Phencyclidine at 24ng/mL
50	THC positive	11-nor-9-carboxy-△9-THC at 35ng/mL
	THC positive	11-nor-9-carboxy-△9-THC at 39ng/mL

Conclusions:

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System has the same intended use and similar technological characteristics as the predicate device. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new issues of safety or effectiveness. Thus, the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MedTox Diagnostics, Inc.
c/o Mr. Phillip Hartzog
Director, R&D
1238 Anthony Road
Burlington, NC 27215

FEB 1 8 2009

Re: k080635
Trade/Device Name: Profile -V MedToxScan Drugs of Abuse Test System
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DJG, LCM and JJQ
Dated: January 15, 2009
Received: January 16, 2009

Dear Mr. Hartzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k080635

Device Name: PROFILE®-V MEDTOXScan® Drugs of Abuse Test System

Indication For Use:

The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System consists of the PROFILE®-V MEDTOXScan® Test Devices and the MEDTOXScan® Reader. The PROFILE®-V MEDTOXScan® Test Devices are one-step immunochromatographic tests for the rapid, qualitative detection of one or more of the following in human urine: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine and THC (Cannabinoids) or their metabolites. The PROFILE®-V MEDTOXScan® Test Devices can only be used with the MEDTOXScan® Reader. The MEDTOXScan® Reader is an instrument used to interpret and report the results of the PROFILE®-V MEDTOXScan® Test Device. The PROFILE®-V MEDTOXScan® Test Devices cannot be visually read.

The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System is for in vitro diagnostic use and is intended for professional use only. It is not intended for use in point-of-care settings.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE, CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k080635

Indication for Use

510(k) Number (if known): k080635

Device Name: PROFILE®-V MEDTOXScan® Drugs of Abuse Test System

Indication For Use:
The PROFILE®-V MEDTOXScan® Drugs of Abuse Test System detects drug classes at the following cutoff concentrations:

AMP Amphetamine (d-Amphetamine) 500 ng/mL
BAR Barbiturates (Butalbital) 200 ng/mL
BZO Benzodiazepines (Nordiazepam) 150 ng/mL
COC Cocaine (Benzoylecgonine) 150 ng/mL
MAMP Methamphetamine (d-Methamphetamine) 500 ng/mL
MTD Methadone (Methadone) 200 ng/mL
OPI Opiates (Morphine) 100 ng/mL
PCP Phencyclidine (Phencyclidine) 25 ng/mL
THC Cannabinoids (11-nor-9-carboxy-□9-THC) 50 ng/mL

Configurations of the PROFILE®-V MEDTOXScan® Test Devices may consist of any combination of the above listed drug analytes.
THE PROFILE®-V MEDTOXScan® Drugs of Abuse Test System provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.
The MEDTOXScan® Reader includes a Positive QC Test Device, a Negative QC Test Device and a Cleaning Cassette. The MEDTOXScan® Positive and Negative QC Test Devices are intended to detect errors associated with the MEDTOXScan® Reader and a contaminated contact imaging sensor (CIS) and to verify that the CIS cleaning procedure using the MEDTOXScan® Cleaning Cassette effectively removed any contamination.

Prescription Use_X_ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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510(k) k080635